

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 7,488,822 Conf. No.: 5696
Issued: February 10, 2009 TC/A.U.: 1464
Appl. No.: 10/767,813 Examiner: Wang, Shengjun
Filed: January 29, 2004
Patentee: Zhang et al
Cust. No.: 38199
Title: CYCLOCARBAMATE DERIVATIVES AS PROGESTERONE RECEPTOR MODULATORS

Mail Stop Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sirs:

**STATEMENT OF FACTS
ACCOMPANYING REQUEST FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT PURSUANT TO 37 C.F.R. § 1.705(d)**

1. This Statement of Facts is respectfully submitted in support of the Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. §1.705(d) for the above-referenced patent. For the reasons set forth below, it is respectfully request that Patentees be granted a patent term adjustment of 1414 days.

2. Erroneous Calculation of Delay

The US Patent and Trademark Office failed to take into account all of the patent term adjustment (PTA) days that Patentees are entitled to pursuant to 35 C.F.R. § 154(b)(1)(B) ("B Delay") when calculating the patent term adjustment. The PTA under 35 U.S.C. §154(b) indicated on the above-identified patent is 859 days (a copy of the face of the patent is submitted herewith as Exhibit "A"). This determination of 859 days is in error as it only reflects a portion of the days to which Patentees are entitled.

3. Examination Delays Pursuant to 37 C.F.R. §1.702 and §1.703

Pursuant to 35 U.S.C. §154(b), the term of patent shall be extended one day for each day that the Office failed to take certain action within the time frame specified in 35 U.S.C. § 154(b)(1)(A) [37 C.F.R. §1.702(a)] (hereinafter “A Delay”) and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 35 U.S.C. § 154(b)(1)(B) [37 C.F.R. §1.702(b)] (hereinafter “B Delay”). In the above-referenced patent, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under 37 C.F.R. §1.703(a) and (b) for the following reasons.

(A) “A Delay”

Pursuant to 37 C.F.R. §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date of the application (hereinafter “14 Month Delay”). Thus, under 37 C.F.R. §1.703(a)(1) Patentees are entitled to a PTA equal to the period between the date which is 14 months from the filing date and the date of mailing of a first Office Action under 35 U.S.C. §132 (*i.e.*, from March 30, 2005 to July 2, 2007 or 825 days).

In addition, pursuant to 37 C.F.R. §1.703(a)(2), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 4 months after the date of reply under 37 C.F.R. §1.111 (hereinafter “4 Month Delay”). Thus, under 37 C.F.R. §1.703(a)(2), Patentees are entitled to a PTA equal to the period between the date which is 4 months from Patentees’ reply and the date of a mailing of an action under 35 U.S.C. §132 (*i.e.*, from August 3, 2008 to September 5, 2008 or 34 days).

The total of 859 days reflected in on the face of the above-identified patent reflects the number of days attributable to delay under 37 C.F.R. §1.703(a)(1) and (2).

(B) “B Delay”

35 U.S.C. §154(b) and 37 C.F.R. §1.702(b) require issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a), *i.e.*, by January 30, 2007. Pursuant to 37 C.F.R. §1.702(b)(1-5), the B Delay

period shall not include certain periods specifically enumerated in the rule, none of which are applicable here. Thus, the B Delay period runs from the day after the date that is 3 years from the actual filing date of the application (January 30, 2007) until the day the patent is granted (February 10, 2009), to provide 743 days¹.

(C) Total Examination Delay Pursuant to 37 C.F.R. §1.703(f)

As set forth in 37 C.F.R. §1.703(f), the period of examination delay based on the grounds set forth in 37 C.F.R. §1.702 is the sum of the period of A Delay (859 days) and the B Delay (743 days), to provide a total of 1602 days, *to the extent these periods of delay are not overlapping*.

Pursuant to *Wyeth v. Dudas*², A Delay days and B Delay days overlap only when they fall on the same calendar day. In the instant case, the period of 14 Month Delay ended on July 2, 2007. The period of B Delay began on January 30, 2007. Thus, A Delay and B Delay overlap for the period of January 30, 2007 to July 2, 2007, i.e. for 154 days. In addition, the entire 4 Month Delay falls on the same calendar days as some of the B Delay period, i.e., for 34 additional days. Therefore, the total period of PTA delay should be reduced by the period of overlap, i.e., 154 days + 34 days = 188 days.

Thus, Patentees are entitled to A Delay + B Delay (to the extent they are not overlapping) = 859 days + 743 days - 188 days = 1414 days of patent term adjustment.

(D) Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. §1.703(f)

As set forth in 37 C.F.R. §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay, which is 0 days. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced patent is 1414 days.

¹ Note that only the days of B delay that do not overlap with A delay days are included in the final PTA calculation. This is further described in section C, below.

² *Civil Action No. 07-1492; 200 US Dist 76063 [D.D.C. September 30, 2008].*

4. This patent is subject to a terminal disclaimer. 37 C.F.R.
§1.705(b)(2)(iii).

5. There were no circumstances during the prosecution of the application resulting in the patent that may be considered to constitute a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. §1.704.

6. In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 1414 days of the patent for the above-referenced application.

Dated: 4/8/2009

Respectfully submitted,
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Alexandria, VA 22313-1450

Sirs:

**APPLICATION FOR PATENT TERM ADJUSTMENT, INCLUDING REQUEST
FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705(d)**

Dear Sir:

1. This is a request for reconsideration of the patent term adjustment under 35 U.S.C. §154(b) of 859 days indicated on the above-identified issued patent. It is respectfully requested that Patentees be granted a patent term adjustment of 1414 days.
2. The above-identified patent issued on February 10, 2009. Accordingly, as required by 37 C.F.R. §1.705(d), the instant request is timely filed within two (2) months of issue date of the above-identified patent.
3. Patentees submit herewith a "Statement Under 37 C.F.R. §1.705(b)(2)".

4. In accordance with 37 C.F.R. §1.705(b)(1), please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 08-3040. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 08-3040.

5. Because this Application for Patent Term Adjustment is being filed to correct an alleged USTPO error, Patentees respectfully request that the Application fee be refunded if this Application for Patent Term Adjustment is decided in Patentees' favor.

Dated: 4/8/2009

Respectfully submitted,
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US00748882B2

(12) **United States Patent**
Zhang et al.

(10) **Patent No.:** US 7,488,822 B2
(45) **Date of Patent:** *Feb. 10, 2009

(54) **CYCLOCARBAMATE DERIVATIVES AS PROGESTERONE RECEPTOR MODULATORS**

(75) **Inventors:** Puwen Zhang, Audubon, PA (US); Eugene A. Terefenko, Quakertown, PA (US); Andrew Fensome, Wayne, PA (US); Jay E. Wrobel, Lawrenceville, NJ (US); Horace Fletcher, III, Pottstown, PA (US); Lin Zhi, San Diego, CA (US); Todd K. Jones, Solana Beach, CA (US); James P. Edwards, San Diego, CA (US); Christopher M. Tegley, Thousand Oaks, CA (US)

(73) **Assignee:** Wyeth, Madison, NJ (US)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 859 days.

This patent is subject to a terminal disclaimer.

(21) **Appl. No.:** 10/767,813

(22) **Filed:** Jan. 29, 2004

(65) **Prior Publication Data**

US 2004/0186101 A1 Sep. 23, 2004

Related U.S. Application Data

(60) Continuation of application No. 10/386,799, filed on Mar. 12, 2003, now Pat. No. 6,713,478, which is a division of application No. 09/948,309, filed on Sep. 6, 2001, now Pat. No. 6,566,358, which is a division of application No. 09/552,633, filed on Apr. 19, 2000, now Pat. No. 6,509,334.

(60) Provisional application No. 60/183,012, filed on May 4, 1999.

(51) **Int. Cl.**
C07D 265/12 (2006.01)

(52) **U.S. CL.** 544/92

(58) **Field of Classification Search** 514/183; 544/92

See application file for complete search history.

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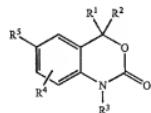
Primary Examiner—Shengjun Wang

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ABSTRACT

This invention provides compounds of Formula (I):



wherein R¹ and R² are independent substituents or are fused to form spirocyclic rings; R³, R^C, and R² are as defined herein; and R⁵ is a substituted benzene ring or a substituted five or six membered heterocyclic ring having in its backbonne 1, 2, or 3 heteroatoms including O, S, SO, SO₂ or NR⁶; or pharmaceutically acceptable salt thereof, as well as pharmaceutical compositions and methods using the compounds as antagonists of the progesterone receptor.

1

2 Claims, No Drawings